Recommendations
of the
EU-Japan Business Round Table
to the Leaders of the European Union and Japan

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Working Party B
Life Sciences and Biotechnologies, Healthcare and Well-being

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List of Abbreviations

Abbreviation	Meaning
ABS	Access and Benefit Sharing
ARCB	Association of Registered Certification Bodies under PAL
CBD	Convention on Biological Diversity
CE	Conformite Europeenne
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFSA	European Food Safety Authority
EU	European Union
FSC	Food Safety Commission
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HTA	Health Technology Assessment
IFAH	International Federation of Animal Health
iPS	induced Pluripotent Stem
J-PAL	Japanese Pharmaceutical Affairs Law
JPMA	The Japan Pharmaceutical Manufacturers Association
LS & BT	Life sciences and Biotechnologies
MAFF	Ministry of Agriculture, Forestry and Fisheries
MDD	Medical Device Directive
METI	Ministry of Economy, Trade and Industry
MHLW	Ministry of Health Labor and Welfare
MIC	Ministry of Internal Affairs and Communications
MNC	Multinational Corporation
MOF	Ministry of Finance
MRA	Mutual Recognition Agreement
NB	Notified Body
NHI	National Health Insurance
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Co-operation Scheme
PMDA	Pharmaceutical and Medical Device Agency
QMS	Quality Management System
VPD	Vaccine Preventable Diseases
WP	Working Party

Introductory Statement

Both, Japan and the EU are facing numerous challenges due to e.g. an aging population, shifting demands in just about all domestic markets and rising costs in many aspects of the welfare system with a need to accelerate and focus on high-end innovations. This particularly in the areas of

- Healthcare
- Plant Protection, and
- Biotechnology.

The enclosed recommendations of WP-B have the clear aim to improve the innovation capabilities of both the EU and Japan through concrete action plans in life sciences and biotechnology, which focus on measures to enhance efficient healthcare practices, food technology / supply and biotechnology.

Recommendations from both European and Japanese industries

Healthcare

WP-B / # 01* / EJ to EJ Regulatory harmonization and MRA for pharmaceuticals

The regulatory harmonization and further extension of "Mutual Recognition Agreement" should be proceeded in order to avoid redundant inspections of manufacturing facilities. In addition to oral dosage forms, API, Sterile and Bio products are being requested to apply to the MRA. Full support is requested to expand the MRA of GMP to liquids, and sterile forms, API and bio products to avoid redundant inspections and testing

<Recent Progress>

Some progress has been seen for this recommendation in that MHLW applied for PIC/S in March 2012. PIC/S was applied in April 2012 and the practical inspection by the global team has been completed. PMDA is expecting the approval in Q1/2014. As the guideline enforces the harmonization of the inspections among PIC/S countries, this issue might be settled in Q1/2014.

<Background>

As currently only oral solid dosage forms are included within the MRA between Japan and the EU, there are still a lot of redundant inspections of manufacturing facilities. This is not only a costly process, but it also slows down the launching of new drugs in Japan creating a significant disadvantage for Japanese patients.
In order to eliminate this problem and integrate EU-Japan economics more efficiently, harmonization of standards / guidelines and expansion of MRA should be conducted under mutual agreements. Below-mentioned are highly prioritized items for harmonization. Also, the MRA issue is one of items of the EPA negotiation between EU and Japan.

<Other prioritized items for harmonization and MRA>

Harmonization:
- Safety measures from surveillance to vigilance should be harmonized with international standards
- Clinical development guideline and biological preparation standards for Vaccine
- Minimum Requirements for Biological Products

WP-B / # 02* / EJ to EJ Mutual recognition of quality management audit results for medical devices between EU and Japan

Improve mutual recognition of Quality Management System (QMS) audit results for lower risk medical devices, e.g. those classified as Class II, ARCB under the Japanese Pharmaceutical Affairs Law, as a first step.

All industry-related manufacturers request PMDA and MHLW to further harmonize and streamline the QMS audit results. MHLW has notified that RCBs can accept non-Japanese QMS audit results. However, ISO13485 continues to be only one part of the Japanese QMS ministerial ordinance. Hence, part of the Japanese requirements. To resolve this issue, it is recommendable that QMS be evaluated on the basis of ISO13485.
In addition to above, the recognition system of "Application for Accreditation of Foreign Manufacturers" should be considered. Even if QMS is evaluated on ISO13485, all industry-related manufacturers have to be registered and are obliged keeping the additional Japanese requirements.

<Recent Progress>

Good progress has been seen for this recommendation. Improving QMS is included in the J-PAL revision and the industry should work with the government to prepare ordinance, which aligns with our recommendation. We recommend using ISO13485 audit report for QMS audit as an international standard as soon as possible.

<Background>

Based on Medical Devices Directive (MDD) of the EU and the Japanese Pharmaceutical Affairs Law (J-PAL), QMS audit results are required for each application for a license to introduce new medical devices in the market. In Europe the regular annual ISO audit results can be used for all applications during the period in which the ISO audit is valid. Recently, Japan has started to accept QMS audit results at a specific manufacturing site for products with the same generic name under certain conditions. However, a number of RCBs still require submitting QMS audit results for each application. Further alignment is necessary.

WP-B / # 03* / EJ to EJ Mutual recognition of medical devices product licenses

Introduce a mutual recognition of medical device product licenses between the EU and Japan. PMDA and MHLW should introduce a mutual recognition of medical device product licenses with low risk of class II devices by taking the difference of classification of medical devices between Japan and the EU into account. By harmonizing QMS and classification it should be possible to introduce new products within the same time frame and in one process. It is desirable that this issue will be solved quickly. Level difference between NBs should also be considered. It *should be recognized that the regulatory approval scheme of class II medical devices in Japan is far from that in the EU, i.e. no need to be reviewed by NBs for Conformite Europeenne (CE) marking of class II medical device in the EU but reviewed by NBs in Japan.*

<Recent Progress>

No progress / no dialogue has been seen for this recommendation. It is desirable that Japan accepts the use of audit report ISO13485 (ISO14155 for clinical trials) issued by the countries (USA, EU, Canada, Australia) with equal standards. To do so, JIS standard should be eliminated from the QMS basic check list and thus rationalize the licensing process.

<Background>

Mutual recognition of licenses for medical devices in Japan and the EU would make it possible to introduce new products in both the Japanese and European markets within the same time frame and with one process.

As mentioned before, it could be possible to start with lower risk, class II devices.

The evaluation scheme between the Medical Devices Directive of the EU and the Japanese Pharmaceutical Affairs Law are quite similar, with
- Evaluation schemes based on registered 3rd party bodies (Notified Bodies)
- Essentially quite similar requirements
- Based on ISO/IEC or JIS standard compliance
With these similarities, a mutual recognition should be easy to implement.

WP-B / # 04* / EJ to EJ <u>Mutual recognition of clinical trial results for medical devices</u>

Introduce a mutual recognition of clinical trial results for medical device development. Foreign clinical trial data have been accepted as a part of application dossier when; i) standards for conducting medical device clinical trials are set by the regulations of the country or region where the trial was performed, ii) the standards are equivalent or surpass the Japanese medical device GCP, and iii) the clinical trial was conducted in accordance with the standards or considered to have equivalent level of quality.
The GOJ encourages active use of consultation service on individual medical device applications in advance provided by the Pharmaceuticals and Medical Devices Agency (PMDA) to address use of foreign clinical trial data for application of the device.

At present, clinical data are often accepted because the standards of clinical trials in the United States or the EU are seen to be equivalent or sometimes more sophisticated than those required by the Japanese medical device GCP. However, then additional data are required with unclear reasons.

In this regard, the ordinance was released in December 2012 by MHLW and some improvements are expected. Further improvements are required in order to accelerate mutual recognition of clinical trial results for medical devices.

<Recent Progress>

<u>Some progress has been seen in the area of mutual recognition of clinical trial results but there is still a difference in Japan's perception of mutual recognition.</u>

<Background>

Differences in the definition of Good Clinical Practice between Japan and the EU currently prevents the use of non-Japanese clinical trial results in the application for new medical devices in Japan. Mutual recognition of clinical trial results would make it possible to make new products available to patients in Japan and the EU within the

same time frame and through one process, ensuring high level of quality while reducing the burden on manufacturers.

Healthcare

WP-B / # 05 / EJ to E Evaluation of innovation values for pharmaceuticals in prices**

The EU government should reinforce its innovation policy to member states and clarify its healthcare policy, resulting in the appropriate evaluation of the value of pharmaceuticals.

<Recent Progress>

No progress has been seen for this recommendation. The Directorate-General for Economic and Financial Affairs of the European Commission, ECFIN, issued a report on drug cost containment methods of member states and recommended a "EU reference price". As such, we would suggest to follow a reimbursement / pricing system which clearly recognize innovation and innovative new products.

<Background>

In the EU, innovation policy is stated by the Lisbon declaration and the G10 group report indicating the importance of innovation in pharmaceuticals. However, each state operates its own healthcare system in different ways, resulting in gaps in survival rates and the QOL of citizens. Under the current economic condition, prices of pharmaceutical products are targeted as a major tool for medical cost containment. BRT members call on the EU and Japan to clarify its healthcare policy and to discuss and totally improve healthcare situations in member states by securing appropriate healthcare budgets, preventing interference with patient access to new medicines and considering the proper utilization of healthcare technology assessment.

Plant Protection & Biotechnology

WP-B / # 06* / EJ to E Shortening review times of plant protection & biotechnology products

Shorten review times for new applications/ registrations.

<Recent Progress>

Some progress has been seen for this recommendation.

<Background>

Research and development of innovative and beneficial Plant Protection & Biotechnology products require high input costs. Therefore, timely access to the markets is crucial for R&D-intensive companies in order to successfully market their products and recover their initial R&D investments, which then again are used to finance further innovations.

Establishment and maintenance of science-based, predictable and timely regulatory systems free from undue political influence and the appropriate protection of proprietary data are therefore key requirements for sustainable and innovative research.

Animal Health

WP-B / # 07* / EJ to E Introduction of "1-1-1 concept" for all animal health products

Introduce 1-1-1 concept for all products (one dossier – one assessment – one decision on marketing authorization applicable to all EU countries). A concept should be worked out between the respective governments / authorities.

<Recent Progress>

Some progress has been seen for this recommendation.

<Background>

One of the key objectives of the European Union is to create a single market for goods. This goal has yet to be achieved for the animal health industry, with the exception of centrally authorized products. In line with the concepts already existing in the EU (i.e. quality, safety and efficacy described in one single EU dossier as the basis for granting marketing authorizations for veterinary medicinal products, one single assessment of the dossier employing the best expertise, resulting in one decision for marketing authorization) the animal health industry in Europe is seeking a systemic change based on the one, one, one concept ("1-1-1 Concept") for all products. This appears to be the most simple and straightforward way to address all of the major shortcomings of the current system and to finally achieve the goal of a single market for safe and efficacious veterinary medicines.

Healthcare

WP-B / # 08** / EJ to J Full-fledged implementation of the new drug pricing system and abolishment of market expansion re-pricing

The premium for new drug creation and elimination of unapproved/off-label use drug will be continued until March 2016. It is welcomed as it supports incentives for innovative drug development; however, it is only the continuation of a trial scheme. The Japanese government should finalize the implementation of the new, internationally competitive drug pricing system in Japan based on the industry proposal since in addition to innovation rewards it is also protecting public health. Furthermore, it adds an element of predictability and stability so that the industry can adequately plan, forecast product requirements and effectively manage inventory as well as the distribution of products

across Japan.

The abolishment of the market expansion re-pricing was not accepted by the Central Social Insurance Medical Council (Chuikyo) even though industries insisted to eliminate the system. While the agenda for the 2014 NHI pricing discussion between Chuikyo and the industry included topics such as “NHI pricing for long-listed products” and “continuation vs. discontinuation of incentives for innovative drug development” it did not include “abolishment of market expansion re-pricing”. Therefore, we urge to discuss this topic to abolish the re-pricing rule by market expansion in the next pricing system reform in 2016, which is contrary to the policy of evaluating pharmaceutical innovation.

<Recent Progress>

No progress has been seen for this recommendation. The new drug pricing system should be implemented firmly and permanently (not only a 2-year trial).Furthermore, the re-pricing system rule by market expansion can adversely affect innovation in Japan and therefore, should be abolished.

<Background>

The NHI price reform proposed by the industry has been positively reviewed by Chuikyo in December 2009 and the government decided to start a pilot implementation in April 2010. This represented a significant improvement, as it provides price stability for innovative drugs and was seen as a positive signal that the Japanese government is willing to reward innovation in the medical field. The premium for new drugs will be continued until 2016. As a compensation for this new scheme, the government will attach a system that fosters the registration of “unapproved/off-label use drugs”. Companies have received requests on developments of many unapproved/off-label use drugs and forwarded those constructively. Furthermore, companies received additional requests on developments of another hundreds of unapproved/off label use drugs for several times.

However, in the FY2014 drug pricing system reform, Chuikyo concluded to postpone full-fledged implementation of the premium for new drug creation to FY2016 revision, even though the industry strongly requested. The conclusion brings the industry deep concerns about sustainability for evaluation of innovations. The Japanese government should implement the new premium system for innovative new drugs at the FY2016 drug pricing system revision to evaluate the companies’ efforts for elimination of the so-called drug lag in Japan and research and development of innovative new drugs.

WP-B / # 09 / EJ to J Appropriate assessment of innovative values of medical devices in prices**

Promote sub-dividing the current functional classification, enhance the premiums for C1 or C2 products (class-C products) and introduce a product-based listing system for new products in order to move towards a product-based, market-oriented reimbursement pricing system in the future.

<Recent Progress>

Some progress and regress has been seen for this recommendation.

<Background>

Different from pharmaceutical brand-oriented pricing systems, about 300,000 medical devices are classified into about 800 functional classes in Japan and one reimbursement price is set for one functional class, based on structure, intended use, effectiveness and so on.

Currently, various old and new products, having various realized prices, have the same reimbursement price within one functional class, which means that the price drop of old products influences the reimbursement price of new ones on the revision of the reimbursement price. This is the reason why the introduction of a product-based reimbursement pricing system is desired.

In Japan's 2014 price revisions, the government's efforts to progress forward the assessment of innovative values can be seen, such as making exception of functional class rule for the excellent and innovative class-C products to keep the independent functional class within the twice price revisions. On the other hand, they strengthened the influence of foreign reference pricing.

We hope the Japanese government will make further efforts to promote medical device development.

Plant Protection & Biotechnology

WP-B / # 10* / EJ to EJ Acceleration and dissemination of scientific knowledge on GMOs by both the governments and the private sector

Governments and the private sector should speed up research in Plant Protection & Biotechnology and inform populations regularly and accurately about the state of play on GMOs, based on sound scientific knowledge.

To that effect Japanese and European biotechnology and bio-industry associations should work closely with other sectorial organisations and their respective Authorities.

<Recent Progress>

No progress has been seen for this recommendation.

<Background>

A stable supply of food is an urgent requirement. While world population keeps growing, the limits of enhancing conventional culture on existing farmlands are being reached. GMOs offer the hope of breaking these limits, but remaining doubts about their safety hamper the development of their utilisation. Considering this situation, it is an urgent matter to speed up research on GMOs and inform people regularly and accurately about the state of play of that research.

WP-B / # 11* / EJ to J <u>Support research in Plant Protection & specifically Biotechnology</u>

Support research in Plant Protection & Biotechnology.

<Recent Progress>

<u>No progress has been seen for this recommendation.</u>

<Background>

Overall in Japan the cooperation between governmental institutes and MNC is limited. Applied science is widely done for instance by PPS (Plant Protection Stations) in all prefectures, however, this is not basic research. Also agricultural universities in Japan do some research on an independent basis.
MAFF is spending around 400 Mio. Yen for residue trials on substances used for rice to confirm the level of the residue in rice for feed and the transfer into livestock (cow and chicken) but the ownership is with the government or some independent institutes. The project is motivated by the policy to increase food sufficiency rate. In the future, MAFF should spend more money on basic research / fundamental technologies in order to facilitate research activities in general. In biotechnology, considerable money is spent on plant molecular biological research but the budget is recently decreasing and no GM products are developed in Japan. It should be taken into consideration to develop GM rice in order to increase yield and decrease production costs. In the past, the rice genome project was supported by the government but the project has been finalized, a smaller post genome project is still running. The outcome of the project is only contribution to develop a marker assisting the breeding of rice. From such research where a considerable amount of Japanese tax payers' money is invested, yielding practical applications is desirable through co-operations among governmental institutes, universities, Japanese domestic companies and MNC.

Recommendations from European industry

Animal Health

WP-B / # 12* / E to J Regulatory harmonization for animal health products

The food animal product registration process is particularly cumbersome, involving a sequential review by MAFF followed by the FSC and the MHLW. Decision criteria and timelines for the following stages of the review process are not provided, resulting in extended review times and often different conclusions from regulators in other countries.

We propose to harmonize and streamline regulatory requirements for product registration of animal health products. MAFF should start harmonization with related countries as this is the path to the 1-1-1 concept recommended previously.
On Oct. 3rd 2013, J-MAFF already shared the idea at the explanatory meeting of revised JPAL for the first time that J-MAFF, FSC and MHLW started discussion how to shorten review times for livestock products (i.e. Introduction of parallel deliberation amongst the authorities) but they didn't show any timeline on the matter.

Clinical trials should be conducted at least at two sites and one of the trials should be conducted in Japan.

<Recent Progress>

Some progress has been seen for this recommendation. In the notification, J-MAFF made clear that marketing authorization will be granted with clinical trial data conducted at least in two sites in foreign countries to confirm the reliability, on the condition that the clinical trials were conducted according to overseas GCP. However, following clinical trials is not beneficial for new notifications. Clinical trials of biologicals and clinical trials of new quinolones, in case the first-choice drug was ineffective.

<Background>

While such global new veterinary medicinal products go already through rigorous review processes in Europe and the USA prior to registration, it requires substantial additional testing in Japan under the Pharmaceutical Affairs Law before an approval is granted. Restrictions on withdrawal period for innovative oil-adjuvant vaccines are especially stringent in Japan. Increased harmonization of regulatory requirements would certainly improve access of animals and animal owners to innovative animal health products which are readily available in Europe.

An additional important aspect is the negative impact on animal welfare: since the regulatory requirements are not harmonized, the companies are required to repeat some tests on animals in Japan, even though results of identical tests are already available and are fully compliant with stringent frameworks like GLP or VICH.

Recognition of animal welfare aspect is not yet optimal in the administration of animal health products in Japan. Japan should minimize the use of animals by accepting more overseas data and alternative approach.

WP-B / # 13* / E to EJ <u>Mutual recognition of GMP and marketing authorization for animal health products</u>

With regard to the Mutual recognition of European and Japanese marketing authorizations and recognition of GMP certification for veterinary products, MAFF should work out harmonized regulations leading to the 1-1-1 concept.

The resources freed in MAFF could probably be diverted to speeding up the processing of dossiers in general, where MAFF has a severe lack of resources adding to the delay in drug availability. However, no indication is found that MAFF is planning to make changes.

<Recent Progress>

<u>Some progress has been seen for this recommendation. However, further strong efforts are required to reach mutual recognition of GMP.</u>

<Background>

While laboratory testing is largely acceptable if conducted under GLP and according to VICH standards, Japan still requires local clinical trials as there is no mutual recognition of Good Manufacturing Practice (GMP) for veterinary medicinal products. Moreover, any overseas production facilities that are involved in manufacturing veterinary medicinal products imported into Japan have to be accredited by MAFF even though their GMP status is authorized by European authorities. This process involves a large amount of administrative work. This research is obsolete as a new research was undertaken in 2012, which showed much improvement. An EU – Japan Economic Integration Agreement should aim for mutual recognition of European and Japanese marketing authorization for veterinary products by starting off with mutual recognition of GMP certification of veterinary medicines. Harmonized regulations on animal vaccines should also be addressed under such an agreement.

WP-B / # 14* / E to EJ <u>Responsible use of antibiotics in animal health</u>

MAFF should promote responsible use of antibiotics in animal health. Furthermore, the establishment of a cascading system, prioritizing the use of approved drugs and formulations where they exist, rather than other available products lacking such claims, would be a method promoting responsible use of all drugs in animal health.

<Recent Progress>

<u>Some progress has been seen for this recommendation.</u>

<Background>

In common with the rest of the world, Europeans and Japanese are concerned by the development of resistance to antibiotic medicines used in human health and the potential threat that the use of antibiotics in animal health will accelerate this process. The use of antibiotics as growth promoters has been prohibited in the EU since 2006.

As a responsible industry, the animal health industry seeks to work with veterinarians, farmers and the feed industry to dispel the myths about the use of antibiotics in animals and promote their responsible use.

In 2013, J-MAFF and Marketing Authorization Holders have shown activities. It can be an option for J-MAFF to implement the consent from Marketing Authorization Holders in order to facilitate prudent use of FQs (Floroquinalone). Although Marketing Authorization Holders were able to define the addition of a precautionary statement in the section of “dosage and administration”, such as, veterinaries should assess the efficacy of the drug within 3 days after the treatment started and the drug should be changed in case of in-efficacy based on the veterinarian’s judgment. J-MAFF released the general notification but no concrete plan was informed.

Healthcare

WP-B / # 15* / E to J Application of GMP on medicinal gases (manufacture of medicinal gases) in Japan

Reinforce the regulation for GMP on medicinal gases in Japan. MHLW has started these initiatives along with industries. But industries are protective to non-GMP facilities because of financial implications.

<Recent Progress>

Some progress has been seen for this recommendation. In February 2012, MHLW noticed to medical gas suppliers to obey voluntary standard by the industry. This standard is almost compatible to GMP standard. PMDA / MHLW will reinforce the GMP for medicinal gases through the PIC/S introduction in Japan in Q1/2014.

<Background>

Medicinal gases are drugs or medicinal devices and have to be compliant with governmental regulations. Main regulations are national Pharmacopeia, GMP (Good Manufacturing Practices), and GDP (Good Delivery Practices). Annex 6 describes GMP and GDP for medical gases: production and distribution. The currently loose interpretation of GMP in Japan along with relatively low standards of Japanese Pharmacopeia is of lower standards as compared to those applicable in Europe or the US. We would like to suggest a reinforcement of regulations on GMP for medical gases in Japan.

WP-B / # 16* / E to J <u>Requirement of Japanese version of the clinical trial protocol and investigators brochure</u>

The Japanese health authority requires a clinical trial protocol and investigator's brochure in Japanese. Translation from English is required for clinical trial notification in Japan. The acceptance of English-only materials for global clinical trials performed in Japan requires further English language education of Japanese regulators. However, if applications could be made in English-only, it would substantially accelerate the process and make innovative drugs available to patients earlier in Japan.

MAFF, MHLW and FSC should start harmonized ways to shorten review times.

<Recent Progress>

<u>No progress has been seen for this recommendation but currently, an English application format is being positively discussed.</u>

<Background>

The Japanese health authority requires a clinical trial protocol and investigator's brochure in Japanese. Translation from the original English version is required for clinical trial notification of global trials in Japan. Therefore, the requirement is considered to be a cause for delay of the start for patients' enrolment in Japan.

WP-B / # 17* / E to J <u>Shorten or eliminate national tests for vaccines</u>

For imported vaccines, national tests in both Japan and manufacturing sites have been conducted (for more than 20 years in some cases). National tests for vaccines should be eliminated or reduced to an absolute minimum.

<Recent Progress>

<u>Some progress has been seen for this recommendation.</u>

<Background>

Vaccine production is done according to GMP and PMDA periodical audits of production sites. However, the higher quality assurance of vaccines is strongly demanded by society. Concerning the national test results which are published by MOU (memorandum of understanding), manufacturing countries should be accepted by the Japanese authority and the national tests for vaccines in Japan should be eliminated or reduced to an absolute minimum.

<u>Animal Health</u>

WP-B / # 18* / E to J <u>Shortening review times for animal health products</u>

Shorten review times for new product applications. MAFF, MHLW and FSC should start harmonization to shorten review times. The process is complicated in addition to a

review period that already for pet animal products (not requiring ADI and MRL) is among the longest in the world. A lot of questions are asked in the process that might be academically interesting but are not necessarily safety or efficacy related. Clarifying registration requirements and shortening review times for importation of recombinant vaccines from Europe should also be implemented.

<Recent Progress>

No change or improvement was seen for this recommendation.

<Background>

In Japan, marketing authorization of a veterinary medicinal product is granted by the Ministry of Agriculture, Forestry and Fisheries (MAFF). For an animal drug intended for use in food-producing animals, the Food Safety Commission (FSC) and the Ministry of Health, Labour and Welfare (MHLW) are also involved in establishing the acceptable daily intake and maximum residue limit, respectively. The review process, involving three different authorities, is rather complex and certainly has some room for efficiency improvement. Also, the review can take an extremely long time until completion. Hence, it delays the access of animal owners and animals to innovative animal health products. This is also true with the introduction of recombinant vaccines from Europe due to lengthy processes of implementing the Cartagena protocol even if the vaccine has already been extensively used in Europe.

WP-B / # 19* / E to J Japanese customs clearance's (cc) rule for investigational drugs and related materials does not allow efficient investigational drug supply

MAFF should harmonize with VICH guidelines.

<Recent Progress>

Some progress has been seen for this recommendation.

<Background>

To import investigational drugs either 1) the Original Clinical Trial Notification sealed by both sponsor and PMDA or 2) YAKKAN is necessary. Recent clinical trials require frequent investigational drug delivery from overseas investigational drug warehouse to study sites. Since both 1) and 2) should be archived by the sponsor and CC agents do not keep those, frequent and timely CC is not possible. If a certified copy of 1) or 2) (certified by sponsor and kept by CC agent) is accepted by the custom, investigational drug delivery will become efficient.

Recommendations from Japanese industry

Healthcare

WP-B / # 20* / J to E Shorten the approval time to register new micro-organism and introduce new technology for producing seasonings and amino acids

Shortening the approval time needed for registration of new materials and introduction of new technologies which aim for product expansion, cost reduction, environmental concerns or diversification of the fermentation material. Clarification of the approval process is also requested.

<Recent Progress>

Some progress has been seen for this recommendation. Shortening the risk assessment time by EFSA and clarification of the evaluation process are accelerated.

<Background>

The long term process for approving a set of safety evaluation such as the bacteria manufacturing process, test products and co-products, delays the enhancement of production and consequently, competitiveness in the EU market. The slow approval process makes companies hesitate to invest in the EU market. On the other hand, it also weakens the export competitiveness of EU companies. For information: US companies are introducing new technologies aggressively. In a typical case, one application takes 30 month-long review time to complete approval processes by regulatory authority in EU, EFSA.